Enabling Oral Drug Delivery to Improve Patient Compliance

Corporate Presentation

July 23, 2019
Forward-Looking Statements

This presentation contains forward-looking statements about Lipocine Inc. (the “Company”). These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to the Company’s product candidates, FDA review process related to our resubmitted NDA for TLANDO™, the expected timing of Phase 2 studies for LPCN 1144 and LPCN 1148, clinical and regulatory processes and objectives, potential benefits of the Company’s product candidates, intellectual property and related matters, all of which involve known and unknown risks and uncertainties. Actual results may differ materially from the forward-looking statements discussed in this presentation.

Accordingly, the Company cautions investors not to place undue reliance on the forward-looking statements contained in, or made in connection with, this presentation. Several factors may affect the initiation and completion of clinical trials and studies, the potential advantages of the Company’s product candidates and the Company’s capital needs. The forward-looking statements contained in this presentation are qualified by the detailed discussion of risks and uncertainties set forth in the Company’s annual report on Form 10-K and other periodic reports filed by the Company with the Securities and Exchange Commission, all of which can be obtained on the Company’s website at www.lipocine.com or on the SEC website at www.sec.gov. The forward-looking statements contained in this document represent the Company’s estimates and assumptions only as of the date of this presentation and the Company undertakes no duty or obligation to update or revise publicly any forward-looking statements contained in this presentation as a result of new information, future events or changes in the Company’s expectations.
## Clinical Stage Biopharmaceutical Company

**Metabolic and Endocrine Focus**

<table>
<thead>
<tr>
<th>PRODUCT (Indication)</th>
<th>PRE-CLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>NDA</th>
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<tbody>
<tr>
<td><strong>TLANDO</strong> <em>(Oral Testosterone for Testosterone Replacement Therapy “TRT”)</em></td>
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<td><strong>PDUFA November 9, 2019</strong></td>
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<tr>
<td><strong>TLANDO XR (LPCN 1111)</strong> <em>(Long Acting Oral Testosterone for TRT)</em></td>
<td></td>
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<td><strong>Phase 2 Complete</strong></td>
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<tr>
<td><strong>LPCN 1144</strong> <em>(Oral Testosterone for pre-cirrhotic NASH)</em></td>
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<td></td>
<td><strong>LiFT Phase 2 Paired Biopsy Clinical Study in NASH Initiated</strong></td>
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<tr>
<td><strong>LPCN 1148</strong> <em>(Oral Testosterone for NASH Cirrhosis)</em></td>
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<td><strong>POC Study Planned</strong></td>
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<tr>
<td><strong>LPCN 1107</strong> <em>(Oral HPC for Prevention of PTB)</em></td>
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<td><strong>EOP2 meeting Completed</strong></td>
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TLANDO™ Franchise Status
Differentiated Oral Testosterone Replacement Candidates

TLANDO: PDUFA Date: November 9, 2019

TLANDO XR Once-a-Day Phase 2 Complete

Not subject to any 3\textsuperscript{rd} party data exclusivity
Fixed Dose Oral Product Targeted for Testosterone Replacement Therapy
Hypogonadism Affects Up to 20 MM American Men\(^1,2\)

TLANDO™ Has The Potential To Drive Market Expansion

- 6MM Men with diagnosed hypogonadism\(^3\)
- 2.2MM Men currently being treated\(^4\)
- 1.5MM Available switch patients
- 700,000 Available naïve patients per year\(^5\)
- 3.8MM diagnosed but untreated patients

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Monthly TRT TRx Trend

TRT Market is Growing

Source: IMS database
TRx = Total prescriptions
Issues with Current Non-oral TRT Options

Potential Barrier To Newly Diagnosed and Existing Patients

- **Black Box Warning**
  - Secondary exposure to testosterone
  - Pulmonary oil micro embolism (POME) and anaphylaxis shock

- **Inconvenient application or painful injection**

- **Poor persistence reflects need for oral**
  - Average days on therapy is 100 days

- **More than 50% of patients need dosage adjustment**
  - Burdensome for patients due to multiple doctor visits
Discontinuation Rates as High as 50% After Only 30 Days with Topical TRT

TLANDO has Potential to Expand the Market Through Improved Persistence

Cohort Period: February 2016 – January 2017
Analysis Period: 12 Months
Look Back: 6 months for new patients

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>% Persistent Patients</th>
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<tbody>
<tr>
<td></td>
<td>Day 30</td>
</tr>
<tr>
<td>New</td>
<td>50.8%</td>
</tr>
<tr>
<td>Experienced</td>
<td>73.0%</td>
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</tbody>
</table>

Source: Adheris Health 2017
Current TRT Dosing Regimes
Over 50% of Patients Require Dose Adjustment with Current TRT Therapies

* Current TRT n=412
Q16. Since you started using your current testosterone medication, how many times was the dose adjusted up or down until you reached your current dose level?

Number of Current TRT Dose Adjustments by Form*

* Gel (n=200)
  - 0 X: 47%
  - 1 X: 33%
  - 2 X: 15%
  - 3 X: 2%
  - >3 X: 3%

* Injectable (n=137)
  - 0 X: 37%
  - 1 X: 26%
  - 2 X: 20%
  - 3 X: 12%
  - >3 X: 5%
### TLANDO Attributes

#### Patient and Physician Preferred Oral Option

**Key Advantages of Oral Route:**
- No risk of accidental T transference
- Non-invasive; easy to use
- Less cumbersome/burdensome
- Potential for higher persistence/adherence

**PCP preferred fixed dosing regimen**
- 450mg (225 mg BID) Daily TU capsule orally administered
  - Unlike most TRT products, fixed “right” dose from the start of therapy with TLANDO for all patients
- Easy to use for patients and physicians to prescribe
- Fewer doctor visits (no dose adjustment visits for patients)
  - More compliant-generalizable to real world male patient behavior
- Not prone to titration decision errors (typical wrong titration decision error range from 10-20%)-risk of patients stuck on wrong dose
- Less prone to drop out after first RX since due to lack of efficacy in patients needing up titration to be efficacious with titrated TRT products
- Fixed/predictable cost for payers with no titration

**Differentiated hypertension (“HTN”) profile**
- ~ 1% new anti-HTN starts or increase in anti-HTN dose
- 32% of subjects with baseline sBP >140 mm Hg experienced a decrease to <140 mm Hg with mean change of -3 mm Hg

**Consistent inter-day restoration of T levels**
TLANDO = Opportunity in a Market Ready for Change
Near Term FDA Decision

TLANDO™ (testosterone undecanoate) 112.5 mg oral capsule

- $2B+ Market Opportunity with growing scripts
- Significant unmet patient and physician needs
- Differentiated fixed dose product profile
- Share of voice all time low; detail sensitive; concentrated call points
- TLANDO™ PDUFA date is November 9, 2019
TLANDO XR
First Long Acting Oral TRT
TLANDO XR (LPCN 1111): Profile

Once Daily Differentiated Oral TRT

• Once daily oral testosterone
  – New molecule with associated IP
  – Novel prodrug of testosterone for oral delivery through proprietary drug delivery technology

• TLANDO XR proof of concept established
  – Positive Phase 2b study results in hypogonadal men
    • Once daily oral dose provides T levels in the eugonadal range

• Phase 3 daily dose identified based on multiple dose Phase 2 studies in hypogonadal male

• Next steps:
  – Obtain FDA feedback on Phase 3 clinical study design
LPCN 1144
Targeted for Non-Alcoholic Steatohepatitis ("NASH")
Non-Alcoholic Fatty Liver Disease ("NAFLD")
No Approved Product for the Treatment of NAFLD/NASH

Fatty liver is a reversible condition wherein large vacuoles of triglyceride (TG) fat accumulate in liver cells via the process of steatosis.

- Healthy Liver
  - 20 – 30% US Adults

- Fatty Liver
  - ↑ TGs
  - ↑ LFTs
  - ↑ Liver fat

- NASH Liver
  - 15 – 20% NAFLDs
  - Steatosis
  - Ballooning
  - Inflammation
  - Fibrosis

- Cirrhotic Liver
  - 10 – 20% NASH
  - Late stage of fibrosis

- Hepatocellular Carcinoma

Eligible for Liver Transplantation

LFTs: Liver function test, especially Alanine amino transferase (ALT) and Aspartame amino transferase (AST)
NASH: Non-alcoholic Steatohepatitis, TG: Triglyceride
Estimated LPCN 1144 Target Market

Reportedly 75% of NASH Male Patients Have Total T less than 372 ng/dL\(^1\)

2. Estes et al, Hepatol 2018
3. About 50% of males are accounted in the whole NASH population.
Unmet Need in Pre-Cirrhotic NASH
Currently No Approved Product to Treat Pre-Cirrhotic NASH

Rationale for Using LPCN 1144 Alone or in Combination to Treat Pre-Cirrhotic NASH

- Multi-dimensional mechanism of action/efficacy across the full NASH disease spectrum
- Tolerable and suitable for chronic use
- Majority of biopsy confirmed NASH adult males have low testosterone
- Sarcopenia in patients with NAFLD is associated with a higher likelihood of having steatohepatitis or advanced liver fibrosis
- Sexual dysfunction is an underappreciated comorbidity in male NASH patients

LPCN 1144: Multidimensional Mechanism of Action Across the Full Spectrum of NASH Pathogenesis

Homeostasis Modifier\(^1,2\)
- Alter lipid, cholesterol, and glucose metabolism
- Reduce visceral abdominal fat
- Modify activity of hepatic lipase, and skeletal muscle/adipose lipoprotein lipase

Anti-inflammatory\(^2\)/Antioxidant/Immuno-modulator\(^3\)
- Restore mitochondrial turnover and normalizes oxygen consumption\(^4\)

Regeneration Booster\(^5,6\)
- Stimulate satellite cells and myocyte precursor resulting in cell differentiation and myocyte proliferation\(^7\)
- Increases circulating endothelial progenitor cells (“EPC”)\(^8\)

Anabolic Agent\(^9\)
- Increase muscle mass, bone density in men with liver disease\(^{10}\)

2. Kelly and Jones, J Endocrinol, 2013
3. Sinclair et al., J Gastroenterol Hepatol, 2015
4. Linda Vignozzi et al., University of Florence, IT, unpublished, 2018
5. A. Francavilla et al., Digest Dis Sci, 1989
6. Vic et al., Hepatol 1982
7. Sinha-Hikim et al., J Clin Endocrinol Metab, 2004
8. Liao CH et al., Andrology, 2013
9. Gentile MA et al., J Mol Endocrine, 2010
10. Sinclair et al., J Gastroenterol Hepatol 2016
LFS was an open-label, multi-center single-arm 16-week study (N=36) with LPCN 1144 in hypogonadal males.

- LF = liver fat
LPCN 1144: Liver Fat Study Results
Meaningful Relative Liver Fat % Change and Responder Rate

**Mean Relative Liver Fat % Change**

- BL ≥ 5%: -33%
- BL ≥ 8%: -42%
- BL ≥ 10%: -40%

**Responder Rate for Relative Liver Fat % Change***

- BL ≥ 5%: 71%
- BL ≥ 8%: 80%
- BL ≥ 10%: 75%

* Responder rate for relative change is % of patients with at least 30% for relative change from baseline.
LPCN 1144: Next Step
Advancing Forward

- *LiFT* (Liver Fat intervention with oral Testosterone) Phase 2 paired-biopsy Phase 2 clinical study in NASH subjects – In progress
  - Study Design
    - Three-arm, double-blind placebo controlled
    - Biopsy confirmed NASH male subjects with NAS ≥ 4
    - Paired biopsy at baseline and EOS (36-weeks)
  - First-patient dosing expected in 3Q 2019
LPCN 1144: A Differentiated Oral NASH Therapy Candidate
Prodrug of Endogenous Testosterone

Liver Fat Reduction and Key Serum Biomarkers

- Over 40% relative mean liver fat reduction after 16-weeks of treatment
- 48% of the treated NAFLD subjects had NAFLD resolution, defined as < 5% liver fat

Suitable for Chronic Use

- Good GI tolerability
- No mean LDL increase
- No signs of nephrotoxicity
- No signs of skeletal fragility
- No signs of drug induced liver toxicity

700+ subjects in 14 studies with up to 52-week exposure

Potential Favorable Benefits in Systems Outside the Liver

- T therapy known to improve symptoms of sarcopenia and, sexual/mood dysfunction
Upcoming Milestones
Near Term Value Drivers

<table>
<thead>
<tr>
<th>Event</th>
<th>Expected Timing</th>
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<tbody>
<tr>
<td><strong>TLANDO™</strong></td>
<td></td>
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<tr>
<td>PDUFA Date</td>
<td>November 9, 2019</td>
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<tr>
<td><strong>LPCN 1144</strong></td>
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<tr>
<td><em>LiFT</em> Phase 2 Paired Biopsy Clinical Study in NASH Subjects - First Patient Dosed</td>
<td>3Q 2019</td>
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</tbody>
</table>
## Key Financial Metrics

### Stock Price, Market Cap, Cash Balance

<table>
<thead>
<tr>
<th>Ticker Symbol</th>
<th>LPCN (Nasdaq Capital Market)</th>
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<tbody>
<tr>
<td><strong>Closing Stock Price (7/19/19)</strong></td>
<td>$1.83/share</td>
</tr>
<tr>
<td><strong>Market Capitalization (7/19/19)</strong></td>
<td>$45.2 million</td>
</tr>
<tr>
<td><strong>Cash Balance (3/31/19)</strong></td>
<td>$22.5 million*</td>
</tr>
<tr>
<td><strong>Bank Debt (3/31/19)</strong></td>
<td>$9.2 million</td>
</tr>
</tbody>
</table>

* $5M restricted and becomes unrestricted upon TLANDO approval
Differentiated Oral Product Targeted for Testosterone Replacement Therapy

Annual TRx ~7M
TLANDO™: NDA Under Review
Near Term FDA Decision

Deficiency 1
Determine extent, if any, of ex-vivo conversion of TU to T

Deficiency 2
Characterize blood pressure effects of TLANDO for appropriate regulatory action

Deficiency 3
Provide justification for non-applicability of Cmax based secondary endpoints

Deficiency 4
Determine the appropriate stopping criteria that can identify patients who should discontinue

PDUFA Target Date
November 9th
Targeted for Non-Alcoholic Steatohepatitis (“NASH”) 

A silent killer that affects 30 million Americans\(^1\)
Clinical Relationship Between Testosterone and NAFLD Across the Full Disease Spectrum

Hepatic Steatosis

“Men with low testosterone are at high risk for NAFLD.” ¹

Free T (pg/mL)

NASH

“Levels of free T decreased significantly with the increased incidence of lobular inflammation, hepatocyte ballooning, NAFLD activity score, and fibrosis.” ²

Low T levels in cirrhotic men are associated with the combined outcome of death or transplantation.” ³

Cirrhosis

1 Kim et al, Gastroenterol 2012; 2 Sumida et al, Gastroenterol Hepatol 2015; 3 Sinclair et al, Liver Trans 2016;
LPCN 1144: Additional Health Benefits
Observed in Hypogonadal Subjects with Elevated ALT*

SF-36, Short Form-36 (0-100); PDQ, Psychosexual Daily Questionnaire (0-7); * ALT > 40 U/L at Baseline in 52 week SOAR Trial (N=33)
LPCN 1144: Extensive Clinical Safety Database Demonstrated No Unexpected Risks

- 650+ subjects in 14 studies with up to 52 weeks exposure
- No drug related SAEs
- No deaths or MACE events

Gastrointestinal Disorders ≥ 1% in SOAR Trial (52 Weeks)
LPCN 1144: Liver Fat Study Results

Liver Fat Based Subject Distribution at Each Visit

Longer Therapy Improved Proportion of Subjects with Disease Resolution

Baseline Pre treatment
- N=34
- LF < 5% (NAFLD Free): 38%
- 5% ≤ LF < 8%
- 8% ≤ LF < 10%
- LF > 10%

8 Week Treatment
- N=33
- LF < 5% (NAFLD Free): 55%
- 5% ≤ LF < 8%
- 8% ≤ LF < 10%
- LF > 10%

16 Week Treatment
- N=34
- LF < 5% (NAFLD Free): 65%
- 5% ≤ LF < 8%
- 8% ≤ LF < 10%
- LF > 10%
LPCN 1148

For Treatment of NASH Cirrhosis
Cirrhotic Liver

Cirrhotic Patients Characteristics:
• Increased morbidity and mortality
• Symptoms of hypogonadism: altered hair distribution, anemia, sexual dysfunction, testicular atrophy, muscle wasting, fatigue, osteoporosis, gynecomastia
• Late stage symptoms: jaundice, pruritis, hepatic encephalopathy, ascites, anasarca, GI bleeding

US Prevalence

Among NASH population (2015)*:
• Fibrosis grade 4 (cirrhosis) case: 1.3M
• Compensated cirrhosis 1.16M
• Decompensated cirrhosis: 134,400

In 2013, cirrhosis cause mortality was ~38,000** and consistently twice the rate in males as females **

*Estes C. et al., Hepatology, 2018;**Yoon and Chen, National Institute on Alcohol Abuse and Alcoholism; surveillance report, 2016
Low Testosterone Increases Adverse Outcome in Male Cirrhotic Patients

T Levels Fall Progressively with Increasing Disease Severity

• Low T reported in up to 90% of NASH cirrhosis patients and is a predictor of mortality

• Low T associated with:
  – Increased risk of major infections, death and/or transplantation rates
  – Increased risk of hepatic decompensation
  – Worsening of sarcopenia
  – Higher Child Pugh score grade
  – Severity of portal hypertension and ascites grade
  – Higher MELD score

1. Sinclair et al., Liver Transplantation, 2016
2. Kim et al., Male Hypogonadism, eds: Winters and Huhtaniemi, 2017
5. Sinclair et.al, Liver international, 2016
LPCN 1148: NASH Cirrhosis
Oral T Therapy

Potentially help patients survive longer while waiting for a liver transplant

- T levels positively correlate with muscle mass in men and modulates bone density, hemoglobin production, insulin resistance, and immunity, commonly impaired in cirrhosis\(^1\)
- Testosterone therapy increased muscle mass in men with cirrhosis and low testosterone\(^2\)

**Next Steps:**
- Proof of Concept study in male NASH cirrhosis subjects

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High PTB Medical Costs

≥ $26 Billion Economic Impact

- 10% of all US pregnancies\(^1\) (475-500K) result in PTB (< 37 weeks)-a leading cause of neonatal mortality and morbidity

- First year medical costs for PTB infants are ~ 10x higher than for full term infants\(^2\)

- 28% of preterm births are to women with histories of early delivery

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1. CDC (2016)
3. Institute of Medicine of the National Academies. July 2006
LPCN 1107: Prevention of Preterm Birth (PTB)
United States Market Landscape

December 31, 2017

- **Makena**: 50%
- **Off Guidance**: 30%
- **Compounded 17-HPC**: 20%

### HPC TRx\(^3\)
- 2016: 44,220
- 2017: 95,935
- 2018: 94,287\(^4\)

### $1B Market Opportunity\(^3\)

1. AMAG estimates Makena market share based on distributor dispensing data and all other market share based on physician market research data conducted by AMAG.
2. Off guidance represents patients treated outside of guidance of Society for Maternal Fetal Medicine, including patients treated with unapproved therapies and untreated patients.
3. IMS data
4. Annualized September 30, 2018 data
LPCN 1107: First Oral PTB Candidate

Characteristics of the Only Approved Product Options for PTB

**IM HPC, Makena®:**
- 20-25% patients below reported better efficacy HPC level threshold
- Total of 18-22 injections
  - Injection location: Upper-outter quadrant of the gluteus maximus
  - Weekly visit to/by health care provider
  - ~35% of patients experienced injection site pain during clinical trial
  - ~17% of patients reported site swelling-much greater than placebo during clinical trial

**SubQ HPC, Makena®:**
- 20-25% patients below reported better efficacy HPC level threshold
- Total of 18-22 injections
  - Approved February 14, 2018
  - Auto injector-ready to use device
  - Injection location: Upper back of the arm
  - Weekly visit to/by health care provider
  - 37.3% of subjects identified injection site pain as a treatment emergent adverse event compared to only 8.2% of subjects in the IM arm
LPCN 1107: First Oral PTB Candidate
Addresses Unmet Need

<table>
<thead>
<tr>
<th>LPCN 1107- Oral HPC</th>
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<tbody>
<tr>
<td>▪ Potential for superior efficacy with Phase 3 target dose</td>
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<tr>
<td>▪ No patient discomfort upon administration</td>
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<tr>
<td>▪ Steady state achieved in 7 days</td>
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<tr>
<td>▪ Orphan drug designation</td>
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<tr>
<td>▪ Major contribution to patient care</td>
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<tr>
<td>▪ Next steps:</td>
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<tr>
<td>▪ Explore partnering opportunities</td>
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</tbody>
</table>
LPCN 1107: Economic Impact
Potential Lower PTB Rate – US and Resulting Savings

Assuming 4.3% lower PTB rate relative to Makena®

~6000 fewer annual PTBs‡

Estimated annual cost saving in ~$310M‡‡

‡: Assuming 100% of 140,000 eligible US population treated
‡‡: Assuming ~$51,600 medical costs/PTB
LPCN 1107: First Oral PTB Candidate

Commercial Outlook/Drivers

**First Oral HPC for Prevention of Recurrent PTB**
- Preferred route-of-administration is oral

**Strong Exclusivity Position**
- Orphan Drug Designation
- Technology/IP protection

**Potential for Superior Efficacy**
- Fewer PTB babies with significant healthcare cost savings

**Strong Pharmaco-Economic Justification**
- Minimize travel related cost/time and healthcare provider cost/time
- Premium pricing potential to generic IM injections
LPCN 1107: HPC PK-PD Correlation

HPC Concentration and PTB Rate with IM HPC, Makena

- Lower % PTB rate can be expected with daily $C_{avg}^2$ HPC levels $\geq 8.2$ ng/mL

2. $C_{trough} \equiv C_{avg}$ for IM Makena®
LPCN 1107: Dose Finding Study Design

PK Study: Oral LPCN 1107 vs IM HPC, Makena

- Open-label, four-period, four-treatment study
- 12 healthy pregnant women- Ages 18-35 years; 16-18 weeks gestation
- All subjects received all four treatments

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<thead>
<tr>
<th>LPCN 1107, Oral HPC</th>
<th>IM HPC, Makena</th>
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<tbody>
<tr>
<td>Treatment A</td>
<td>Treatment D</td>
</tr>
<tr>
<td>400mg BID</td>
<td>250mg Weekly</td>
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<tr>
<td>Treatment B</td>
<td></td>
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<tr>
<td>600mg BID</td>
<td>Multiple dose:</td>
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<tr>
<td>Treatment C</td>
<td>5 weeks</td>
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<tr>
<td>800mg BID</td>
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Multiple doses for 8 days
LPCN 1107: Dose-Finding PK Study Results

Oral LPCN 1107 vs IM HPC, Makena

- HPC levels below 8.2 ng/mL:
  - Target LPCN 1107 Phase 3 dose was 0% vs 20% subjects using IM HPC Makena per label
- Average HPC levels at target LPCN 1107 Phase 3 dose
  - ~3x greater than the comparator, IM HPC, Makena

1. PK results obtained post 8 days of BID dosing for LPCN 1107 and post 5 weeks for weekly IM HPC, Makena